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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/707,121	11/06/2000	Brian Mathur	LEX-0083-USA	8244

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LEXICON GENETICS INCORPORATED
8800 TECHNOLOGY FOREST PLACE
THE WOODLANDS, TX 77381-1160

EXAMINER

PAK, YONG D

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 08/27/2002 15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/707,121

Applicant(s)

MATHUR ET AL.

Examiner

Yong Pak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

The amendment filed on June 18, 2002, amending claim 2, has been entered.

Claims 2-4 are pending.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 18, 2002 has been entered.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 2-4 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

Claims 2-4 are drawn to polynucleotides encoding proteins of unidentified function. The claimed polynucleotides are not supported by either a specific and substantial asserted utility. The specification fails to provide objective evidence of any activity for the encoded proteins or to show that these proteins even exist. Applicant only states that the encoded protein sequence shares structural similarity with animal

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kinases, especially serine/threonine protein kinases (page 2, lines 2-5). Since the specification sets forth no specific function for the encoded protein, the claimed polynucleotides encode a protein with no ascribe function. No specific, substantial and credible utility that is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material is indicated. Identifying a polynucleotide as encoding a kinase-like protein does not endow the polynucleotide with such a utility. Therefore, there is no specific, substantial, or credible utility that is well known, apparent, or implied by the relationship of the instant polynucleotide to the polynucleotide encoding a kinase.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention so that it would operate as intended without undue experimentation. In the state of the art, the function of a polynucleotide is unpredictable from its structure and the functionality of a polynucleotide must be known

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in order to use the polynucleotide. Therefore, the specification does not teach how to use polynucleotides with unknown function.

Response to Arguments

Applicant's arguments filed June 18, 2002 have been fully considered but they are not persuasive.

Claims 2-4 remain rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

Applicants argue that human kinase have utility (Remarks page 3 through 7). The examiner disagrees. The rejection was based on the utility of the particular sequence of SEQ ID NO:1 and not the whole genus of novel human kinases or newly identified genomic sequences. Identifying a polynucleotide as encoding a kinase-like protein does not endow the polynucleotide with such a utility. The specification fails to provide objective evidence of any activity for the encoded proteins or to show that these proteins even exist. Applicant only states that the encoded protein sequence shares structural similarity with animal kinases, especially serine/threonine protein kinases (page 2, lines 2-5).

Applicants also argues that the polypeptide of SEQ ID NO:2 is a kinase by citing WO 01/66594 and WO 02/10401 (Remarks pages 7 and 8). Applicants argue that the polypeptide encoded by SEQ ID NO:1 is a kinase because SEQ ID NO:1 is 99% identical to the said PCTs. The examiner disagrees with the applicant's line of

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reasoning. The polypeptides of WO 01/66594 provide polypeptides that are protein kinases and protein-like genes (page 46). Also, sequence search of SEQ ID NO:1 of the instant invention shows that SEQ ID NO:1 of the instant invention is 99.2% identical to a Rab GTPases of SEQ ID NO:13 of WO 01/20022 (pages 2 and 37). If one were to follow the applicant's line of reasoning, SEQ ID NO:1 could be identified as a Rab GTPase. Therefore, identifying a polynucleotide as encoding a kinase due to its similarity to a particular kinase or a kinase-like protein does not endow the polynucleotide with such a utility.

Applicants also argue that SEQ ID NO:1 encodes a kinase because SEQ ID NO:1 contains a protein kinase domain, as verified by protein structural analysis accepted by those of skill in the art. The specification does not contain such structural analysis.

Since the specification sets forth no specific function for the encoded protein, the claimed polynucleotides encode a protein with no ascribed function. Therefore, there is no specific, substantial, or credible utility that is well known, apparent, or implied by the relationship of the instant polynucleotide to the polynucleotide encoding a kinase.

Claim Rejections - 35 USC § 112

Claims 2-4 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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Applicant's arguments are discussed above.

Since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention so that it would operate as intended without undue experimentation. In the state of the art, the function of a polynucleotide is unpredictable from its structure and the functionality of a polynucleotide must be known in order to use the polynucleotide. Therefore, the specification does not teach how to use polynucleotides with unknown function.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 8:00 A.M. to 4:30 P.M weekdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak
Patent Examiner



August 22, 2002